

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**SEP - 3 2004**

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Assigned 510(k) number

K041627.....

Submitter's Information

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Contact person: Dana Olsen, Regulatory Affairs
Date of preparation: June 10, 2004

Device Name

Trade Name: Cystatin C Immunoparticles (code No. LX 002)
Common/Usual name: Cystatin C Reagent
Classification name: Test, Cystatin C (21 CFR – 862.1225)

Trade Name: Cystatin C Control Set (code No. X 0973)
Common/Usual name: Controls
Classification name: Single (Specified) Analyte Controls (Assayed and Unassayed) (21 CFR 862.1660)

Trade Name: Cystatin C Calibrator (code No. X 0974)
Common/Usual name: Calibrator
Classification name: Calibrator, Secondary (21 CFR 862.1150)

Predicate Devices

For Cystatin C Immunoparticles:
N Latex Cystatin C Test Kit, Dade Behring, Inc. (K003503)
Creatinine Plus, Roche Diagnostics Corp. (K953239)

For Cystatin C Control Set:
N Cystatin C Control, Dade Behring, Inc. (K003503)

For Cystatin C Calibrator:
N Protein Standard UY, Dade Behring, Inc. (K003501)

Cystatin C Immunoparticles - Cystatin C Control Set - Cystatin C Calibrator
DakoCytomation Denmark A/S

Device Description

Cystatin C Immunoparticles are purified immunoglobulin fraction of rabbit antiserum directed against cystatin C covalently coupled to uniform polystyrene particles. The Cystatin C Immunoparticles are provided as a suspension preserved with 15 mmol/L sodium azide and are supplied ready for use. Recombinant human cystatin C produced in *E. coli* was used as an immunogen for raising the antibody coupled to the polystyrene particles.

In the DakoCytomation Cystatin C Assay, human serum or plasma is mixed with the Cystatin C Immunoparticles. The resulting immune complexes are measured by turbidimetry or nephelometry. The generated signal is correlated with the concentration of cystatin C in the sample. By interpolation on a standard curve, the concentration of cystatin C in the sample is calculated.

Cystatin C Control Set is a bi-level control. The controls are liquid pools of delipidated human serum enriched with recombinant human cystatin C produced in *E. coli* and preserved with 15 mmol/L sodium azide. Each donor has been tested and found negative for hepatitis B virus surface antigen, antibodies to hepatitis C virus and human immunodeficiency virus 1 and 2. The Cystatin C Control Set is supplied ready for use.

The cystatin C value assignment has been carried out by turbidimetry using the DakoCytomation Cystatin C Calibrator, code No. X 0974, as reference.

Cystatin C Calibrator is a liquid pool of delipidated human serum enriched with recombinant human cystatin C produced in *E. coli* and preserved with 15 mmol/L sodium azide. Each donor has been tested and found negative for hepatitis B virus surface antigen, antibodies to hepatitis C virus and human immunodeficiency virus 1 and 2. The Cystatin C Calibrator is supplied ready for use.

The cystatin C value assignment has been carried out by turbidimetry using a precise transfer protocol ensuring traceability to a pure recombinant human cystatin C reference preparation, where the cystatin C concentration was established by dry mass determination.

Intended Use

For In Vitro Diagnostic Use. For Professional Use Only.

Cystatin C Immunoparticles are intended for the quantitative determination of cystatin C in human serum, heparinized plasma and EDTA plasma by turbidimetry and nephelometry. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal diseases

Cystatin C Control Set is an assayed bi-level control intended to monitor and evaluate the precision and accuracy of the quantitative immunological determination of human cystatin C by turbidimetry or nephelometry.

The Cystatin C Calibrator is intended for establishing calibration curves for the quantitative immunological determination of human cystatin C by turbidimetry or nephelometry.

Substantial Equivalence Comparison

The DakoCytomation **Cystatin C Immunoparticles** are substantially equivalent to the Dade Behring, Inc., N Latex Cystatin C Test Kit (K003503) with respect to indications for use, device design, materials and operational principles. The basic differences between the new device and the Dade Behring predicate device is the instruments used for testing. The DakoCytomation device can be used on commercially available turbidimetry and nephelometry analyzers, while the Dade Behring, Inc. product is applicable only on the Dade Behring, Inc. Nephelometer Systems. The DakoCytomation Cystatin C Immunoparticles are also claimed substantially equivalent to the Roche Diagnostics Corp. Creatinine Plus (K953239) in the intended use and results obtained. The difference in technology does not introduce new issues of safety and effectiveness.

The DakoCytomation **Cystatin C Control Set** is substantially equivalent to the Dade Behring N Cystatin C Control (K003503), with regard to the technological characteristics and in terms of the intended use.

The DakoCytomation **Cystatin C Calibrator** is substantially equivalent to the Dade Behring N Protein Standard UY (K003501), with regard to the technological characteristics and in terms of the intended use.

Performance Characteristics and Data

Performance characteristics and data presented in support of the Cystatin C Immunoparticles together with Cystatin C Control Set and Cystatin C Calibrator include precision, accuracy, linearity, sensitivity, specificity, security ranges, interferences and stability testing. Assay results obtained with various commercially available turbidimeters and IMMAGE® Immunochemistry System (nephelometer) were analyzed and found to be comparable.

A comparison of performance between the DakoCytomation Cystatin C Immunoparticles, Cystatin C Control Set and Cystatin C Calibrator with the Dade Behring, Inc. N Latex Cystatin C Test Kit (K003503) and N Protein Standard UY (K003501) demonstrated substantial equivalence. Additionally, a comparison of performance between the DakoCytomation Cystatin C Assay, and the Roche Diagnostics Corp. Creatinine Plus assay (K953239) demonstrated substantial equivalence.

Substantial Equivalence

Based on the information provided in this premarket notification, DakoCytomation concludes that the new devices, Cystatin C Immunoparticles, Cystatin C Control Set and Cystatin C Calibrator, are safe, effective and substantially equivalent to the Dade Behring predicate devices N Latex Cystatin C Test Kit (K003503), N Cystatin C Control (K003503) and N Protein Standard UY (K003501) respectively, with regard to the indications for use, device design, materials and operational principles. Additionally, the Cystatin C Immunoparticles are substantially equivalent to Roche Diagnostics Corp. Creatinine Plus (K953239) with regard to the intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Dana Olsen
Regulatory Affairs
DakoCytomation Denmark A/S
Produktionsvej 42
DK-2600 Glostrup
Denmark

SEP - 3 2004

Re: k041627
Trade/Device Name: Cystatin C Immunoparticles
Cystatin C Control Set
Cystatin C Calibrator
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test system
Regulatory Class: Class II
Product Code: NDY, JJX, JIT
Dated: June 10, 2004
Received: June 16, 2004

Dear Ms. Olsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

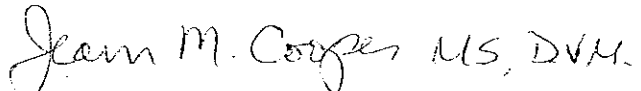
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in dark ink, reading "Jean M. Cooper MS, D.V.M." in a cursive style.

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

510(k) Number K041627

Indications for Use

Device Name:

Cystatin C Immunoparticles

Indications for Use:

For In Vitro Diagnostic Use. For Professional Use Only.

Cystatin C Immunoparticles are intended for the quantitative determination of cystatin C in human serum, heparinized plasma and EDTA plasma by turbidimetry and nephelometry. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal diseases.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

Device Name:

Cystatin C Control Set

Indications for Use:

For In Vitro Diagnostic Use. For Professional Use Only.

Cystatin C Control Set is an assayed bi-level control intended to monitor and evaluate the precision and accuracy of the quantitative immunological determination of human cystatin C by turbidimetry or nephelometry.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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Cystatin C Immunoparticles - Cystatin C Control Set - Cystatin C Calibrator
DakoCytomation Denmark A/S

510(k) Number K041627

Indications for Use

Device Name:

Cystatin C Calibrator

Indications for Use:

For In Vitro Diagnostic Use. For Professional Use Only.

Cystatin C Calibrator is intended for establishing calibration curves for the quantitative immunological determination of human cystatin C by turbidimetry or nephelometry.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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